



Image 1615

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q57234

Yoshihisa NISHIBE, et al.

Appln. No.: 09/446,276

Group Art Unit: 1615

Confirmation No.: 2101

Examiner: Amy E. Pulliam

Filed: December 21, 1999

For: PHARMACEUTICAL COMPOSITION FOR APPLICATION TO MUCOSA

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.97 and 1.98

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith, along with a copy of the corresponding Communication from a Foreign Patent Office (as detailed below):

Office Action in corresponding Canadian application issued on October 17, 2003:

1. WO 98/00178-A1,
2. CA 2,278,025-A1,
3. CA 2,268,140-A1,
4. CA 2,164,624-A1,
5. CA 2,107,587-A1, and
6. CA 1,327,314-A1.

**Office Action in corresponding Japanese application issued on November 4,
2003:**

1. JP 6-172199-A with English-language abstract,
2. JP 63-166832-A with English-language abstract and corresponding patent EP 0277462,
3. JP 8-217678-A with English-language abstract,
4. JP 59-130820-A with corresponding English language patent EP 0115627, and
5. Dictionary of Food Additives, 1st edition, (1994), pp. 36-7 with English summary.

and

Office Action in corresponding Chinese application issued on October 24, 2003:

1. US 5,393,773-A.

The present Information Disclosure Statement is being filed after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, Notice of Allowance, or an action that otherwise closes prosecution in the application (whichever is earlier), and therefore Applicant is filing concurrently herewith a Statement Under 37 C.F.R. § 1.97(e). No fee under 37 C.F.R. § 1.17(p) is required.

In compliance with the concise explanation requirement under 37 C.F.R. § 1.98(a)(3) for foreign language documents, Applicant encloses herewith a copy of three Communications from foreign patent offices in counterpart applications citing such documents, together with an English-language version (if not already included) of at least that portion of the Communication indicating the degree of relevance found by the foreign patent office. In addition, the Application submits:

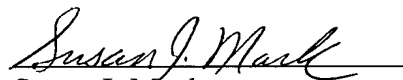
- (1) **an English language abstract along with JP 6-172199-A, JP-8-217678-A and JP 63-166832-A,**
- (2) **corresponding patent EP 0227462 along with JP 63-166832-A,**

- (3) **an English language corresponding patent EP 0115627 along with JP 59-130820-A, and**
- (4) **an English language summary along with the Dictionary of Food Additives.**

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,


Susan J. Mack
Registration No. 30,951

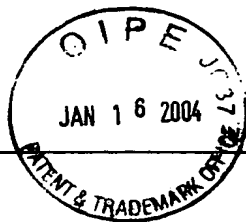
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23373

CUSTOMER NUMBER

Date: January 16, 2004



MODIFIED PTO/SB/08 A& b (06-03)

Substitute for Form 1449 A & B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	09/446,276
Confirmation Number	2101
Filing Date	December 21, 1999
First Named Inventor	Yoshihisa NISHIBE
Art Unit	1615
Examiner Name	Amy E. Pulliam
Attorney Docket Number	Q57234

Sheet	1	of	1
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code ² (if known)		
		US 5,393,773	A	02-28-1995	CRAIG et al.

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)			
		WO	98/00178	A1	01-08-1998	RHONE-POULENC RORER PHARMACEUTICALS INC.	N/A, but w/Abstract
		CA	2,278,025	A1	07-23-1998	SENJU PHARMACEUTICAL CO., LTD.	N/A, but w/Abstract
		CA	2,268,140	A1	04-30-1998	VIROTEX CORPORATION	N/A, but w/Abstract
		CA	2,164,624	A1	01-05-1995	CARRINGTON LABORATORIES, INC.	N/A
		CA	2,107,587	A1	10-04-1992	GUNDERSEN MEDICAL FOUNDATION, LTD., et al.	N/A
		CA	1,327,314	A1	03-01-1994	TEIKOKU SEIYAKU K.K.	N/A
		JP	6-172199	A	06-21-1994		Abstract
		JP	63-166832	A	07-11-1998	CIBA-GEIGY AG	Abstract & Corresponding patent EP 0 277 462
		JP	8-217678	A	08-27-1996		Abstract
		JP	59-130820	A	07-27-1984	ARMOUR PHARMACEUTICAL COMPANY	Corresponding English language patent EP 0 115 627

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation ⁶
		Dictionary of Food Additives, 1 st Edition, (1994), pp.36-7.	Abstract
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²See Kind Codes of USPTO Patent Documents at www.uspto.gov, MPEP 901.04 or in the comment box of this document. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to indicate here if English language Translation is attached.